

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference 10800-013	FOR FURTHER ACTION	See item 4 below
International application No. PCT/CA2004/000824	International filing date (<i>day/month/year</i>) 03 June 2004 (03.06.2004)	Priority date (<i>day/month/year</i>) 03 June 2003 (03.06.2003)]
International Patent Classification (IPC) or national classification and IPC 7 C12Q 1/68, C07D 333/32, C12N 15/11		
Applicant INFECTIO DIAGNOSTIC (I.D.I) INC.		

1.	This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 <i>bis</i> .1(a).																								
2.	This REPORT consists of a total of 7 sheets, including this cover sheet. In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.																								
3.	<p>This report contains indications relating to the following items:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 10%; text-align: center;"><input checked="" type="checkbox"/></td> <td style="width: 30%;">Box No. I</td> <td style="width: 60%;">Basis of the report</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>	<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input checked="" type="checkbox"/>	Box No. VII	Certain defects in the international application	<input checked="" type="checkbox"/>	Box No. VIII	Certain observations on the international application
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<input checked="" type="checkbox"/>	Box No. VIII	Certain observations on the international application																							
4.	The International Bureau will communicate this report to designated Offices in accordance with Rules 44 <i>bis</i> .3(c) and 93 <i>bis</i> .1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44 <i>bis</i> .2).																								

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Date of issuance of this report 08 December 2005 (08.12.2005)
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PATENT COOPERATION TREATY

REC'D 31 JAN 2005

From the
INTERNATIONAL SEARCHING AUTHORITY

WIPO

PCT

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/CA2004/000824

International filing date (day/month/year)
03.06.2004

Priority date (day/month/year)
03.06.2003

International Patent Classification (IPC) or both national classification and IPC
C12Q1/68, C07D333/32, C12N15/11

Applicant
INFECTIO DIAGNOSTIC (I.D.I.) INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/CA2004/000824

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☒ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☒ in written format
 - ☒ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☒ furnished subsequently to this Authority for the purposes of search.
3. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/CA2004/000824

Box No. V Reasoned statement under Rule 43*b*/s.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	5-8,14-17,23-26,31-36
	No: Claims	1-4,9-13,18-22,27-30
Inventive step (IS)	Yes: Claims	
	No: Claims	1-36
Industrial applicability (IA)	Yes: Claims	1-36
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item I

Basis of the report

Sequence listings filed, 2 pages, seq id 1-3, with the letter of 06.12.04, are filed after the filing date of the application and do not form part of the description and will not be annexed to this communication (Rule 13ter(f) PCT).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

- D1: WO 02/081735 A
- D2: HO HOANG-ANH, ET AL., ANGEW. CHEM. INT. ED., vol. 41, no. 9, (2002-05-01), pages 1548-1551,
- D3: EWBANK P C ET AL: "TETRAHEDRON LETTERS", vol. 42, no. 2, (2001-01-08), pages 155-157,
- D4: BOCK L C ET AL: NATURE, vol. 355, no. 6360, (1992-02-06), pages 564-566
- D5: HO HOANG A. & LECLERC M.: J. AM. CHEM. SOC., vol. 125, (2004-03-22), pages 4412-4413
- D6: HO HOANG-ANH & LECLERC M.: J. AM. CHEM. SOC., vol. 126, (2004-01-15), pages 1384-1387
- D7: US5631146

The present application refers to a method for identifying a target by using a target specific aptamer and a polymer of polythiophene structure. The target may be a potassium ion, organic molecule, protein etc. (page 8, l. 5ff.). The target is detected by a red shift of the fluorescence spectrum of the polymer (e.g. page 12, l. 18 ff.). Figure 5 should demonstrate the shift of the fluorescence maxima for a target-containing and a target-free solution. However it seems that the shift is similar for the target containing and target-free solution (see Fig 5 , b,c,d).

Document D1, describes the use of the cationic polythiophene polymer of the present

application as optical sensor for the detection of nucleic acid sequences, see e.g. claims and figures. Also the publication of D2 refers to the use of polythiophenes for detection of nucleic acids. The prior art D1,D2 therefore is considered to fall within the scope of present claim 1 and is considered to be relevant according to Article 33(2)(3), see also item VIII, below. The same holds true for claims 2-4,9-13,18-22,27-30,

The aptamer sequence of claim 5 is known in the prior art (D4). The subject-matter of claim 5 therefore is considered as an obvious combination of known structural features from the prior art, see also D1/D2. An inventive step (Article 33(3) PCT) can therefore not be acknowledged. The same holds true for claims 6,24,25,23,24,31,32 and 35.

A partial homologue sequence of seq id 3 of claim 7 is disclosed in D7, US5631146, see seq id 82 which is suitable for the detection of D-adenosine. Without the identification of a special technical feature of seq id 3 an inventive step for claim 7 can therefore not be acknowledged (Article 33(3) PCT). The same holds true for claims 8, 16,17,25,26,33,34,36.

Re Item VII

Certain defects in the international application

The application should be self contained. Therefore the term "... incorporated by reference in their entirety." on page 2, l. 15 ff does not fulfil the requirements of the PCT-Guidelines C-II 4.17.

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1, is not mentioned in the description, nor are these documents identified therein.

The vague and imprecise statement "...and should not be interpreted as limiting the scope of the present invention." in the description on page 7, first paragraph, implies that the subject-matter or which protection is sought may be different to that defined by the claims, thereby resulting in a lack of clarity (Article 6 PCT) when used to interpret them (PCT Guidelines C-III, 4.3). The same holds true for paragraph 3 on page 8.

Re Item VIII

Certain observations on the international application

The optical sensor of claim 1 is not defined by structural features, no reference is given to the aptamer sequence, and therefore the scope of the claim is unclear (Article 6 PCT). Furthermore on page 2, line 19-20 it is mentioned that the optical sensor is based on a hybrid aptamer/conjugated polymer complex, this structural feature is not defined by the wording of the claim. The scope of the claim is thus not defined in such a way as to allow the skilled person to understand, without undue burden, which optical sensors are used for detecting a target.